EUROPEAN CHEMICALS AGENCY

Helsinki, 23 August 2017

Addressee: [redacted]

Decision number: CCH-D-2114363882-41-01/F
Substance name: 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with (chloromethyl)oxirane
EC number: 608-489-8
CAS number: 30499-70-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 13.05.2016
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method: OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum with the registered substance;**

2. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**

3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

4. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309). The results shall correspond to the temperature of 12°C (285K);**

5. **Identification of degradation products (Annex IX, Section 9.2.3.);**

6. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous or dietary exposure, OECD TG 305) with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **30 August 2019**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Mutagenicity" is an information requirement as laid down in Annex VIII, Section 8.4. of the REACH Regulation. Column 2 of Annex IX, Section 8.4. provides that "If there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the Registrant."

The technical dossier contains several *in vitro* studies with the registered substance that show positive results like the *bacterial reverse mutation assay* (OECD TG 471), *mammalian cell gene mutation assay* (OECD TG 476) and *in vitro mammalian chromosome aberration test* (OECD TG 473). The positive results indicate that the substance is inducing gene mutations and structural but not numerical chromosomal aberrations under the conditions of the tests.

An appropriate *in vivo* genotoxicity study to follow up the concern on gene mutations and structural chromosomal aberrations is not available for the registered substance. In IUCLID section 7.6.2, you are indicating that a comet assay according to OECD TG 489 "*is currently underway for production stewardship purposes in the US and will be incorporated into this dossier when available*". In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you confirm that "*This experimental phase of the test has now been completed and a report is in production, the registration dossier will be updated without undue delay accordingly to include this new data and the appropriate classification once the final report is available*". However, in your current registration, this information has not been provided. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In case there are positive results in both chromosomal aberration and gene mutation *in vitro* studies, the ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, section R.7.7.6.3 identifies that the following tests are options for a follow-up *in vivo* study: The mammalian erythrocyte micronucleus test ("MN test", OECD TG 474), the mammalian bone marrow chromosomal aberration test ("CA test", OECD TG 475) or the *in vivo* mammalian alkaline comet assay ("Comet Assay", OECD TG 489). Based on the information provided in the dossier, it is uncertain whether the test substance or its metabolites will reach the target tissue. Hence, ECHA considers the *in vivo* Comet Assay to be the most appropriate test to follow up the concern for the substance subject to the decision.

According to the test method OECD TG 489, the test shall be performed in rats. Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

According to the test method OECD TG 489, the test shall be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the substance, and probable different local absorption rates of the substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to sample both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vivo* mammalian alkaline comet assay (test method: OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum.

Notes for your consideration

You are reminded that according to Annex IX, Section 8.4., column 2 of the REACH Regulation, if positive results from an *in vivo* somatic cell study are available, "the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered".

You may consider examining gonadal cells in addition to the other aforementioned tissues, as it would optimise the use of animals. ECHA notes that a positive result in whole gonads is not necessarily indicative for germ cell damage since gonads contain a mixture of somatic and germ cells. However, such positive result would indicate that the substance and/or its metabolite(s) have reached the gonads and caused genotoxic effects. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

Careful consideration should be given to the tissue sampling for comet analysis alongside the requirements of tissue sampling for other types of toxicological assessments. Harvest 24 hours after the last dose, which is typical of a general toxicity study, is not appropriate for the comet assay where samples are usually collected 2-6 h after the last treatment (see OECD TG 489, paragraph 33).

ECHA notes that your registration dossier indicates that you have already started performing this study. It is for this reason that in May 2016 ECHA informed you of the termination of the examination of your testing proposal for this study. Following a Member State Competent Authority (MSCA) proposal for amendment (PfA), you confirmed you have completed the experimental testing of the comet assay, where liver, glandular stomach and duodenum were sampled and the registration dossier will be updated without undue delay accordingly to include this new data and the appropriate classification once the final report is available.

You are further under Article 22 of the REACH Regulation reminded to update your dossier without undue delay once the study has been completed.

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex IX, Section 8.6.2. or with the general rules of Annex XI for this standard information requirement.

In your comment(s) in the draft decision according to Article 50(1) of the REACH Regulation, you stated that "*the registrant disagrees with the request to conduct the study based on the findings of the OECD 422 that was submitted within the technical dossier. During this test the mating and fertility data identified that pre-coital interval was unaffected by treatment [...]*" and "*As a consequence of these findings the registrant has classified the substance as reproductive toxin Cat 1B presumed human reproductive toxicant and therefore conduct of further prolonged tests with animals will not provide any additional data for the risk assessment process.*"

However, as indicated above, the submitted screening study (OECD TG 422) does not cover the required exposure duration of 90 days as required in a sub-chronic toxicity study (OECD TG 408). Furthermore, the screening study (OECD TG 422) has a lower statistical power and does not investigate all parameters.

Additionally, in this specific case, the dose limiting scheme of the submitted study is not sufficient for purposes of investigating general toxicity. More specifically, due to the dose-limiting reproductive toxicity observed at 300 mg/kg bw/d, no higher doses could be tested. However, higher dosing might be possible in a repeated dose toxicity study.

In addition, the classification for toxicity to reproduction 1B is not a rule for adaptation according to Annex IX, Section 8.6.2., column 2.

Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. According to the Chemical Safety Report, risk management measures are in place to prevent exposure of humans via inhalation. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex IX, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.7.2. because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation, you refer to the adaptation possibility of REACH Annex IX, Section 8.7., Column 2 that "*If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.*"

You disagree with ECHA's request to conduct a further study because you consider that

(i) it will not be possible to conduct any developmental study at a dose level of 300 mg/kg bw/d, and as no developmental effects were noted at the lower dose levels further testing for developmental toxicity will not provide any additional data for the risk assessment process;

(ii) you self-classified the substance for reproductive toxicity Category 1B and therefore "*conduct of further prolonged tests with animals will not provide any additional data for the risk assessment process*";

(iii) "*Based on this classification stringent risk management measures and PPE will be required to ensure safety during activities associated with the registered uses*"

(iv) "*The testing is based on oral exposure which is already a conservative estimate of toxicity, given that the substance in used in controlled processes whereby in the unlikely event exposure occurred this is likely to be via a dermal route*".

However, ECHA considers that in this case it is necessary to perform further testing which is explained below.

(i) ECHA notes that performance of a pre-natal developmental toxicity study will be possible and will provide relevant information on hazard assessment. More specifically, in a pre-natal developmental toxicity study already pregnant dams will be exposed to the substance. Hence, the demonstrated substance-specific effect on male fertility will not have an impact on the dosing and performance of a pre-natal developmental toxicity study. Furthermore, the available OECD TG 422 screening study is not suitable to conclude on the absence of effects on developmental toxicity. This study provides – with low statistical power - some indications for no obvious developmental effects on offspring up to 100 mg/kg bw/d. However, this study does not provide specific information on skeletal and visceral alterations in foetuses up to sufficient high doses relevant for classification. ECHA notes that in the cross-mating study in which female rats dosed with 300 mg/kg bw/d were mated with control male rats ([redacted] 2016), the following was concluded: "Comparative assessment of litter responses was not possible due to lack of litters for control females (paired with treated males), however the litter data available for treated females was considered not to indicate any obvious adverse effect of treatment". ECHA notes that this conclusion is based on examination of the pregnant dams on gestation day 14 with respect to loss of offspring. Since this investigation does not address exposure until gestation day 20 with subsequent morphological examination of the offspring, this study does not allow any conclusion on potential skeletal or visceral anomalies of the offspring.

(ii) With respect to your self-classification Reproductive toxicity 1B, ECHA notes that based on the specific effect on male fertility, classification for Reproductive Toxicity 1B, H360F, may damage fertility should be applied instead of a combined classification for fertility and developmental toxicity.

Also, the registered substance tested positive in all three in vitro genotoxicity tests, which raises a concern for developmental toxicity through effects on the more rapidly dividing cells of a growing embryo and foetus.

(iii) ECHA acknowledges the Registrant's description of stringent risk management measures and PPP.

(iv) ECHA notes that testing for pre-natal developmental toxicity is intended for hazard identification and is usually performed by the oral route irrespective of the dominating human route of exposure.

Therefore, your adaptation of the information requirement is rejected.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.4.2.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rat or rabbit) by the oral route.

Notes for your consideration:

ECHA further notes that, should the concern for genotoxicity of this substance be confirmed through positive results from the requested *in vivo* mammalian alkaline COMET assay and lead to a classification for known germ cell mutagenicity with appropriate risk management measures in place, the information requirement for the pre-natal developmental toxicity study requested in the present decision could be adapted. The timeline set out in this decision has been set to allow for sequential testing.

4. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Column 2 of Section 9.2. of Annex IX indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 of Section 9.2.1.2 of Annex IX further indicates that the study does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable.

You have sought to adapt this information requirement. You provided the following justification for adaptation: "*In accordance with column 2 of REACH (Regulation (EC) No 1907/2006) Annex IX, the simulation testing on ultimate degradation in surface water, and sediment simulation testing (required in section 9.2.1.2, and 9.2.1.4) does not need to be conducted based on the findings of the Chemical Safety Assessment; the substance does not fulfil classification criteria according to the applicable regulations and does not fulfil the criteria for vPvB or PBT.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of column 2 of Annex IX, Section 9.2 and of Annex IX, Section 9.2.1.2.

First, with respect to your adaptation in accordance with column 2 of Annex IX, Section 9.2 ECHA considers that the information provided in your registration dossier is insufficient to rule out the possibility that some relevant constituents are PBT or vPvB. Consequently, ECHA considers that your CSA cannot rule out the need to investigate further the degradation of the substance and its degradation products.

Second, with respect to your adaptation in accordance with the second column of Annex IX section 9.2.1.2, you have not shown that the substance is highly insoluble or readily biodegradable.

Water solubility of the registered substance is 2.73 g/L, therefore it is not highly insoluble. Three biodegradation tests were provided in your registration dossier. The registered substance was tested according to OECD Guideline No 302B, attained 25% biodegradation after 28 days performed according and was considered to be inherently, primarily biodegradable. The results of the ready biodegradability test according to OECD 301F and 301B showed respectively 8 % and less than 10 % biodegradation after 28 days. Therefore, the registered substance is not readily biodegradable.

ECHA further notes that the registered substance is a multi-constituent substance. In the OECD guideline "Revised introduction to the OECD guidelines for testing of chemicals, section 3" presenting the principles and strategies related to the testing of degradation of organic chemicals, it is indicated that ready biodegradability tests are intended for pure substances and are generally not applicable for complex mixtures containing different types of constituents, like multi-constituent substances. For a multi-constituent substance, observed biodegradation may indeed represent the biodegradation of only some constituents.

Article 43 of this OECD document indicates that "*it is sometimes relevant to examine the ready biodegradability of mixtures of structurally similar chemicals*". Still "*a case by case evaluation should however take place on whether a biodegradability test on such a complex mixture would give valuable information regarding the biodegradability of the mixture as such (i.e. regarding the degradability of all the constituents) or whether instead an investigation of the degradability of carefully selected individual components of the mixture is required*". In your CSA you have assumed that the registered substance is inherently biodegradable but you have not provided evidence that every constituent of your substance is degradable. According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further specifies that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*".

Therefore the persistence shall be assessed for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

Therefore, your adaptation of the information requirement cannot be accepted and information on the persistence of the substance and on its potential degradation products shall be provided.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments according to Article 50(1) of the REACH Regulation, you agree to this request. ECHA acknowledges your agreement.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "*attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids* [...]*, and a typical temperature that represents the particular environment*".

The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Therefore, the test results, and in particular the degradation rates and the substance half-life, shall correspond to the temperature of 12°C (285K).

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

5. Identification of degradation products (Annex IX, Section 9.2.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Column 2 of Section 9.2. of Annex IX indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 of Section 9.2.3. of Annex IX further states that the identification of degradation products does not need to be provided if the substance is readily biodegradable.

ECHA notes that you have not provided information on the degradation products of the registered substance. However, ECHA notes that:

- The substance is not readily biodegradable.
- Pursuant to Annex XIII of the REACH Regulation "the identification [of PBT and vPvB substances] shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products". Your CSA does not contain any information on the degradation products and on whether they could be PBT/vPvB or not.
- Information on degradation products shall also be taken into account for the exposure assessment (Annex I 5.2.4. of the REACH Regulation) and for the hazard assessment (e.g. column 2 of Annex X 9.4 and Annex X 9.5.1 of the REACH Regulation). Finally, information on degradation products is required for the preparation of Section 12 of the safety datasheet (Annex II of the REACH Regulation).

Furthermore, ECHA notes that the CSA with its current information gaps cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA considers that the requested information is needed in relation to the PBT/vPvB assessment and risk assessment.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments according to Article 50(1) of the REACH Regulation, you agree to this request. ECHA acknowledges your agreement.

The aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) requested in section 6 of that decision is an appropriate test method to obtain information on the primary degradation and the formation of major transformation products in water. The analytical methods used for the identification of the degradation products will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of those metabolites may be investigated. As specified in the OECD 309 test guideline, higher concentrations of the test substance (e.g., >100 µg/L) and a test temperature within the frame provided by the study guideline could be used to overcome potential analytical limitations for the identification and quantification of major transformation products.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore degradation products should be identified for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

Therefore, pursuant to Article 41(1)(a) and(b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

6. Bioaccumulation in aquatic species: aqueous or dietary exposure (Annex IX, Section 9.3.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Information on bioaccumulation is necessary for the PBT/vPvB assessment and for the risk assessment and shall be considered for the classification and labelling of the substance. ECHA notes that you have not provided any experimental data on the registered substance for endpoint bioaccumulation.

You provided the following justification for the adaptation: "*The substance is expected to have a low potential for aquatic / sediment bioaccumulation because it has a low octanol water partition coefficient (log Kow = 0.467)*".

In your dossier you determined the octanol water partition coefficient of the test item as being in the range from 2.93 to 2.53 E^{+03}, log_{10} P_{ow} in the range 0.467 to 3.40. and the main constituents have values for log K_{ow} of 2.04, 1.61 and 0.958.

ECHA notes that in your dossier the mean surface tension of duplicate solutions prepared at nominally 1.0 g/l of test item in water has been determined to be 51.4 ± 1.0 mN/m and you have concluded that the substance is surface active.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017) the classification of the bioconcentration potential based on hydrophobicity measures (such as log K_{ow}) should be used with caution for surface active substances and measured BCF values are preferred.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is generally regarded as the preferred route and shall be used whenever technically feasible. It is, however, acknowledged that the BCF value obtained from aquatic studies may also be somewhat uncertain in particular if it is technically difficult to keep a constant concentration in the aqueous phase.

For surface active substances in particular, the OECD 305 test guideline indicates that "*it should be considered whether the aqueous bioconcentration test is feasible, given the substance properties, otherwise the dietary study is probably more appropriate*". The amphiphilic nature of surface active substances (i.e. they contain both a hydrophilic and a hydrophobic part) causes them to accumulate at interfaces such as the water-air interface, the water-food interface, and glass walls, which hampers the determination of their aqueous concentration. Therefore you should investigate whether it is possible to keep a constant concentration of the substance in the aqueous phase before deciding whether an aqueous BCF study or a dietary bioaccumulation study will provide the most reliable and useful results for the PBT/vPvB assessment.

A proposal for amendment (PfA) from a Member State Competent Authority (MSCA) outlined that you should first investigate further the Log Kow and surface tension measurements of the individual components of the registered substance within the applicability of the corresponding specific guideline(s) before conducting a bioaccumulation study.

In your comments according to Article 50(1) of the REACH Regulation, you agreed to this request (ECHA acknowledges your agreement). Subsequently, in your comments on this PfA, you agreed to first investigate these physical chemical properties of the individual components of the registered substance, prior to committing to vertebrate testing.

ECHA notes that it is your responsibility to undertake further clarifying investigations on certain physical chemical properties if you wish so. If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, to ensure compliance with this standard information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Following a Member State Competent Authority (MSCA) proposal for amendment (PfA), ECHA further notes that according to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore the bioaccumulation or bioconcentration should be assessed for each relevant group of homologous constituents and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305)

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

In addition, you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4, R.5, R.6, R.7b and R.7c. If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "*How to use alternatives to animal testing to fulfil your information requirements for REACH registration*".

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 5 October 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-54 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.